ASEPTIC TECHNOLOGIES

FILLING SOLUTIONS
Safer & Easier

Overall Introduction
March 2014
NEW CONCEPT OF ASEPTIC FILLING

DESCRIPTION

**Crystal® CLOSED VIALS**

- Vials are produced and stoppered in ISO5 clean room to ensure cleanliness
- Vials are sterilized by gamma-irradiation before delivery to pharmaceutical users

**Crystal® CLOSED VIAL FILLING LINES**

- Filling is performed by a special needle piercing the stopper
- The stopper is immediately re-sealed by laser
- Capping is done in the ISO5 area according to new authority requirements
The first *ready-to-fill* closed vial which really minimizes the risk of contamination.
CLOSED VIAL
VIAL MANUFACTURING

The first **ready-to-fill** closed vial which really minimizes the risk of contamination

**From aseptic ... to aseptic**
FILL AND CLOSE
NEW CONCEPT OF CRYSTAL® | KEY STEPS SUMMARY

1. SUPPLIED CLEAN, CLOSED & STERILE
2. FILLING THROUGH THE STOPPER
3. LASER RE-SEALING OF THE STOPPER
4. CAPPING BY SNAP-FIT

Simply Safer & Easier! Fully GMP
ASEPTIC FILLING
SIMPLIFIED PROCESS (GMP)

GLASS VIAL FILLING
- vials
  - Loading
  - Washing
  - Siliconization
  - Sterilization
  - Isolator or RABS
    - Cooling zone
    - Filling
    - Transfer
    - Stoppering
    - Capping by crimping
- Downstream equipment

- stoppers
  - Loading
  - Washing
  - Siliconization
  - Sterilization
- WFI

Crystal® FILLING
- Loading
- Washing
- Siliconization
- Sterilization
- CVFS
- Filling
- Laser re-sealing
- Capping by snap fit
- Downstream equipment

Elimination of

- WFI
- Vial and stopper washing
- Vial and stopper sterilization
- Stoppering
- Capping by crimping

Lean manufacturing
THE CRYSTAL® TECHNOLOGY
ADVANTAGE YOU CAN’T DENY

COST REDUCTION

Investment costs

LESS equipment
less clean room space needed

Operation costs

LEAN manufacturing

MUCH EASIER
CRYSTAL® TECHNOLOGY

USERS

SYNFLORIX™ pediatric vaccine is approved by EMA in the Closed Vial for all European countries

More than 40 equipment in use
CRYSTAL® CLOSED VIAL
DESIGN FOR MORE ADVANTAGES

Tightness for storage at
very low temperatures.

Large piercing area.

Minimized residual liquid.

Protection

Closure integrity

Laser re-sealing
Thermoplastic Elastomer (TPE)

Unbreakable
Cyclo-olefin Co-polymer (COC)

Mechanical stability
Small vials

Every small detail matters
CRYSTAL® VIAL RANGE

A complete range of ready-to-fill vials
CRYSTAL® CLOSED VIAL TECHNOLOGY

VIALS PROPERTIES

- Right angle “non return” snap-fits
- Large piercing area protected by cap
- Hydrophobic material to prevent electrostatic interactions
- Stopper designed to minimize residual volume of liquid
- Made of COC, resistant to damages

Isolator at item level
ADVANTAGES OF VIAL DESIGN
CLOSURE INTEGRITY AT VERY LOW TEMPERATURE

POLYMER VIAL BODY RESISTANT TO LOW TEMPERATURE STORAGE

Stopper crimped between vial body and top ring ensuring uncompromised closure integrity

Stopper compression secured by snap-fit assembly
V-pressure rib hanging the stopper

Suitable for storage at very low temperature
CRystal® Closed Vials

Behavior at Very Low Temperature

At -80°C and in Liquid Nitrogen

- Closure integrity ✓
- Weight variation ✓
- Tightness ✓
- Visual aspect ✓

Polymer vial body resistant to extremely low temperature storage.
TPE stopper ensures uncompromised closure integrity.

**Crystal® Closed Vials** particularly suitable and widely used for cryogenic storage of injectables.

Good resistance for storage at very low temperature.
CRYSTAL® CLOSED VIAL FILLING LINE
LABORATORY LINES

Crystal® M1 FILLING STATION

- Independent tools with manual operations
- To be installed in existing environment (BSC)
- Designed to fill small batch filling
- May reach batch size up to 2,000 vials

Crystal® L1 ROBOT LINE

- Robot line with all tools on robot head
- Fully automated
- Capacity: up to 600 vials/hour *
- Space needed: ~8 m² (footprint: 1 m²)

* 1 ml vials

Stability, clinical & niche productions
CRYSTAL® M1 FILLING STATION
MANUAL FILLING STATION

FOR R&D ... AND PRODUCTION (GMP COMPLIANT)

In use at user's sites
CRYSTAL® CLOSED VIAL FILLING LINE
M1 FILLING STATION | VIDEO

WATCH M1 FILLING STATION VIDEO ON

CRYSTAL® L1 ROBOT LINE

DELIVERED TO THE NETHERLANDS VACCINE INSTITUTE

Up to 600 vials per hour

Fully automated small batch production
Crystal® PX FILLING LINE

- Designed to fill commercial batches
- Capacity: currently up to 180 vials/min
- Footprint: 16 m² (3.6 m x 4.2m)
- Installation in various containment
SAFE & EASY

Closed Vials from 1ml up to 50ml.
Max. 180/min (8 pumps).
Easy tool less format change.
100% In Process Control.

Limited footprint (16 m²).
No water for injection, no compressed air needed.
Low electrical consumption (no heating).
Suitable for aseptic operation in Grade C surrounding (Closed RABS).
ASEPTIC FILLING
EASY SCALING-UP

From **Manual** filling station
to Automated Production line up to **180 vials/min**

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M1 Filling Unit  
L1 Robot Line  
PX Filling line (production)

*1 ml vials

For every life-cycle step of your product
A safe and easy alternative to glass vials
CRYSTAL® VIAL SUITABLE FOR

- Potent and hazardous drugs (cytotoxics, radiolabeled, immuno-modulating drugs, recombinant viruses,...)
  - Unbreakable container
  - No spillage outside during filling inside a closed container

- Frozen products (-20°C, -80°C and in liquid nitrogen)
  - No loss of closure integrity (no stopper retraction)
  - Container remains resistant
  - No damages during thawing

- Expensive drugs (antibodies, recombinant proteins,...)
  - Lower risk of batch rejection thanks to simple process
  - Residual volume minimized

- All aseptically filled products
  - Ready-to-fill container, ensuring lean and safe process
  - Improved quality thanks to a container permanently closed

Multiple products may benefit
CONCLUSIONS

• Offer SAFER and EASIER solution for your injectable products

• Has a proven track record of product stability

• Is fully validated to meet authority requirements and the Validation Master File was used to get SYNFLORIX™ approval by EMA

Filling suite in our facility to support your stability studies in our Crystal® vials

ASEPTIC TECHNOLOGIES
CONCLUSIONS

SAFER
EASIER

CRISTAL® CLOSED VIAL TECHNOLOGY
Simply Safer!

CONTACT US to get free vial samples for compatibility testing

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